REMARKS

Applicant's attorneys wish to thank Examiners Tung and Benzion for their time and courtesy during the telephonic interview that took place on May 29, 2003. The following remarks are intended to constitute a proper recordation of such interview in accordance with MPEP §713.04, and also to provide a full response to the Office Action mailed on December 2, 2002.

The interview focused primarily on PCT application WO 91/15601 by Shuldiner et al. ("Shuldiner"). Applicant's attorneys argued that Shuldiner does not teach or suggest the pending claims, and proposed advancing prosecution by canceling claims 16-27 without prejudice and recasting claims 22 and 24 as dependent claims of the surviving independent claim 28. This is accomplished in the foregoing amendment.

Claim 28 is also amended to recite "[a] method for detecting cross-sample contamination in an amplification reaction" to more particularly point out and more distinctly claim the subject matter which Applicant regards as his invention. Support for this amendment can be found throughout the specification and at least on pages 2, 5, and 6. Applicant submits that no new matter is added by the present Preliminary Amendment.

Rejections Under 35 U.S.C. § 102

Claims 16, 18, 19, 21-23, 25, 28, 29, 31-34, and 37 are rejected under 35 U.S.C. § 102 as being anticipated by Shuldiner. Claim 16, 18, 19, 21-23, and 25 have been canceled without prejudice. Among the remaining claims, amended claim 28 is the only independent claim.

Shuldiner describes an amplification method that distinguishes cDNA made from endogenous RNA in a sample from contaminating DNA in the same sample and amplifies only the endogenous RNA sequences (pg. 6, lns. 23-27). Specifically, the method involves using a hybrid primer containing a 5'-unique random sequence in a reverse transcription, resulting in DNA tagged with the unique random sequence (pg. 7, lns. 22-29). Subsequently, a primer specific for the random sequence is used in a PCR reaction conducted in the same sample containing the tagged DNA in order to selectively amplify the tagged DNA (pg. 8, lns. 14-17, and 26-27).

Shuldiner does not teach or suggest the methods recited in amended claim 28 for detecting cross-sample contamination in amplification reactions. The Examiner states in the final Office Action that the method of Shuldiner can be used in the detection of cross-sample contamination. Applicant respectfully traverses. According to Shuldiner's method, after the reverse transcription, the DNA tagged with the unique random sequence is positively amplified. Because none of the contaminating DNA is tagged, Shuldiner's method does not perform the last step recited in either amended claim 16 or amended claim 28, which is determining whether contamination has taken place. Shuldiner's method amplifies the target template regardless whether there is any contamination in its sample. Obtaining an amplicon using Shuldiner's method does not give one any information on whether there is contamination in the sample or not.

Moreover, the amplification reactions in Shuldiner's method have to be conducted in the same sample, as it avoids possible contaminating DNA by amplifying only sequences derived from endogenous RNA in the same sample (pg. 8, lns. 26-27). The Examiner states in the final Office Action that the pending claims do not recite that the samples are different. Applicant submits that by reciting a step of determining whether a sample has been contaminated by another sample, the original claims 16 and 28 each recite a method that one of ordinary skill would understand to require two different samples, because a sample cannot "contaminate" itself. However, in the interest of advancing prosecution, Applicant submits clarifying amendments to claims 16 and 28 to explicitly recite different samples in each claimed method. Thus, as already discussed in a previous Response dated August 30, 2002, Shuldiner not only fails to teach or suggest determination of contamination, but also fails to teach or suggest detection of cross-sample contamination.

Accordingly, Applicant respectfully submits that Shuldiner does not supply a sufficient basis for a rejection of the pending claims under 35 U.S.C. § 102. Therefore, Applicant respectfully requests that all rejections under § 102 be reconsidered and withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 24, 26, 27, 35, and 36 are rejected under 35 U.S.C. § 103 (a) as being obvious over Shuldiner in view of U.S. Pat. No. 4,965,188 to Mullis et al. (hereinafter "Mullis").

As described above, Shuldiner does not teach or suggest detection of cross-sample contamination as presently claimed. Mullis describes general methods for amplifying a target nucleic acid sequence in a nucleic acid mixture. *See* Abstract. Its methods use two primers that are complementary to portions of the two strands of a target sequence, but it does not teach or suggest any method for detecting contamination in an amplification reaction. Therefore, the combination of the two references fails to disclose or suggest all the claim elements. Accordingly, Applicant respectfully submits that the 35 U.S.C. § 103 rejections cannot be sustained against the pending claims. Therefore, Applicant respectfully requests that all rejections under § 103 be reconsidered and withdrawn.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 17, 20, and 28-37 were rejected under 35 U.S.C. § 112, second paragraph, for failing to set forth the subject matter which Applicant regards as his invention.

a. Claims 17 and 20 have been canceled without prejudice, rendering their rejections moot.

b. The Examiner states that claims 28-37 are vague and indefinite because the language "the amplification of which is desired," in claim 28, is unclear as to which amplification it is referring to. Applicant submits, without amendment to claim 28, that the quoted phrase modifies the "target nucleic acid" that precedes the quoted phrase. In other words, the amplification of the "target nucleic acid" is desired.

c. The Examiner states that it is unclear what is meant by "at least one primer in said control reaction is not complementary to any contiguous nucleic acid sequence in said template" in claim 30. Applicant submits, without amendment to the claims, and as put forward in the previous Response dated August 30, 2002, that neither primer recited in claim 30 is complementary to any continuous stretch of nucleic acid sequence in a target template, although

separate parts of the target template, say, two nucleotides here and three nucleotides there, may together be complementary to part or all of the primer sequence.

In light of the foregoing reasons, Applicant respectfully submits that the existing language of claims 28-37 is clear and definite to one skilled in the art, and respectfully submits that all rejections under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

CONCLUSION

In view of the amendments and remarks submitted herein, Applicants respectfully submit that all pending claims 28-39 are in condition for allowance and request the application proceed to issue. The Examiner is invited to call the undersigned if the Examiner believes that a telephone conversation could be helpful in discussing any outstanding issues in connection with the instant Application.

Respectfully submitted,

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